

Application No. 08/354,450
Amendment dated September 20, 2004
Reply to Office Action of March 19, 2004

REMARKS

Applicant amended claims 40, 41, 56, 72, 73, 95, 114, 115, 139, 156, 173, 191, 208, 222, 239, 253, and 270 to further define Applicant's claimed invention.

I. Objections to the specification and rejections under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 132.

In the Office Action, the Examiner objected to the amendment filed on January 7, 2004 under 35 U.S.C. § 132 as introducing new matter and objected to the specification under 35 U.S.C. § 112, first paragraph for failing to provide support for the invention as now claimed.

In particular, the Examiner contends that the specification as originally filed does not support the subject matter identified under items (a) to (l) listed on page 2 of the Office Action. Applicant respectfully traverses the Examiner's objection for the subject matter of items (a) to (g) and (i) to (l). For item (h), Applicant amended claims 56, 95, 139, 173, 208, 239, and 270 to recite the rivet having a length "of approximately 8 mm," which is supported in the specification at least on page 8, line 4.

For items (a) and (b), Applicant discloses that the flexible member is flexible "so as to be able to conform to the angle of the meniscus M," and "deform so as to conform to the surface of the meniscus." (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry, 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the

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perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Applicant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is "at least in part curved" and that the flexible member can have a top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Applicant further submits that the flexible member being at least in part curved (item (a)) and deformable to have an at least in part concave shape (item (b)) when in contact with the tissue is inherently supported in the specification and drawings of Applicant's disclosure as originally filed. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-150, col. 1 (May 2004)) (emphasis added). Accordingly, Applicant submits that the Examiner's objection to the subject matter identified in items (a) and (b) as lacking support has been overcome.

For items (c) and (d), the flexible member having a greater surface area to mass ratio than that of the shaft (item (c)) and the flexible member having a smaller mass than that of the shaft (item (d)) is supported in the original disclosure at least, for example, in Fig. 4. (A copy of Fig. 4 is attached hereto as Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone

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may provide a 'written description' of an invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United States*, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-139, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Examiner's understanding of the difference in the surface area to mass ratios, Applicant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). Applicant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. As the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Applicant submits that the disclosure as originally filed supports the relationships set forth in items (c) and (d).

For items (e) and (f), Applicant respectfully disagrees with the Examiner's contention that the original disclosure does not support the flexible projections being oriented in at least two arrays (item (e)) and at least four arrays (item (f)) along the mid-longitudinal axis of the shaft. Applicant discloses four arrays running along the length of the shaft in Fig. 5. A copy of Fig. 5 is attached hereto as Exhibit C with arrays 1-4 labeled for the Examiner's convenience. Nonetheless, in order to expedite prosecution, Applicant amended claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 to change "along" to "around" as indicated by the Examiner as being supported in the disclosure as originally filed. (See Office Action, page 3, last full paragraph). The claims now recite that the projections are oriented in arrays "around the mid-longitudinal axis of said shaft."

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For item (g), Applicant respectfully disagrees with the Examiner's contention that the original disclosure does not support at least two flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft. Applicant discloses at least two flexible projections *extending* from the shaft in the same plane in Fig. 1. A copy of Fig. 1 is attached hereto as Exhibit D with a transverse plane drawn thereon showing two of the flexible projections extending from the shaft along a plane "P."

Moreover, Applicant notes that the Examiner's position in the present action is inconsistent with the Examiner's earlier position stated in the Office Action dated July 7, 2003. In that Office Action, the Examiner stated that "[i]t would appear in all of the drawings the projections all extend in the same perpendicular plane. Therefore there are always four projections in a plane perpendicular to the longitudinal axis." (Office Action dated July 7, 2003, page 4, paragraph 2). Applicant submits that the disclosure as originally filed supports at least two of the flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft.

For item (i), Applicant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); a copy of page 588 is attached hereto as Exhibit E). Applicant discloses in Fig. 7 an included angle between the bottom of the flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, a copy of which is attached hereto as Exhibit F).

For item (j), the outer perimeter of the flexible member remaining substantially in a single plane when moving relative to the shaft is supported in the original disclosure at least, for example, in Figs. 6 and 7. As shown in Fig. 6, the outer perimeter of the flexible member is in a plane. (A copy of Fig. 6 is attached hereto as Exhibit G and

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shows a plane "C"). When moving relative to the shaft, the outer perimeter of the flexible member remains in plane C as shown, for example, in Figs. 6 and 7 (Exhibits G and F, respectively). Applicant submits that the disclosure as originally filed supports the outer perimeter of the flexible member remaining in substantially in a single plane when moving relative to the shaft.

For items (k) and (l), the bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft (item (k)) and a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft (item (l)) is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit F). As shown in Fig. 7, there is an acute angle (angle A in Exhibit F) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft and an obtuse angle (angle B in Exhibit F) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Applicant submits that the disclosure as originally filed supports the angular relationships set forth in items (k) and (l). Applicant submits that the Examiner's objection to the amendment filed on January 7, 2004 under 35 U.S.C. § 132 and the objection to the specification under 35 U.S.C. § 112, first paragraph for failing to provide support for the invention as now claimed has been overcome.

The Examiner rejected claims 29-300 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not adequately described as set forth in the objection to the specification under 35 U.S.C. § 112, first paragraph. Applicant submits that the rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph has been overcome in view of the remarks set forth above in relation to the objection to the specification under 35 U.S.C. § 112, first paragraph (incorporated herein by reference) and the amendment of claims 40, 41, 56, 72, 73, 95, 114, 115, 139, 156, 173, 191, 208, 222, 239, 253, and 270.

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The Examiner rejected claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully requests the Examiner to withdraw this rejection because the Examiner's rationale for supporting the rejection relate to issues of inadequate written support and not to indefiniteness, which is an issue under 35 U.S.C. 112, first paragraph, not second paragraph. For each of the Examiner's contentions listed as being rejected under 35 U.S.C. 112, second paragraph, the Examiner is referred to Applicant's remarks above in relation to the objection to the specification and the rejection of claims 29-300 under 35 U.S.C. 112, first paragraph, which are incorporated herein by reference.

II. Rejections under 35 U.S.C. § 103(a).

The Examiner rejected claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren"). Applicant respectfully traverses the rejection and submits that it cannot be maintained at least for the reasons stated below.

A. Warren teaches away from the claimed invention.

Warren discloses a surgical fastener for attaching soft tissues to bone or bone-like structures. (Warren, col. 7, lines 22-31). In order to insert the fastener into the bone, Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, column 5, lines 8-16; and Figs. 6-8). Accordingly, the structure of head 110 must be able to withstand repeated blows to drive the fastener into bone.

Warren discloses two ways that the head is made sufficiently rigid to withstand pounding. First, head 110 is made thick. Warren teaches that the thickness of head 110 is 0.069 inches, which is more thick than any part of the shank wall 115

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perpendicular to the longitudinal axis of the fastener. (Warren, col. 3, lines 38-40; Fig. 1). Secondly, Warren teaches the use of a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110. (Warren, col. 3, lines 40-42). As is known in the art, fillets are used to reinforce a corner where two surfaces meet. (See, e.g., Merriam Webster's Collegiate Dictionary, 10th ed., page 435, col. 1 (1999); a copy of page 435 is attached hereto as Exhibit H). Accordingly, the head of the Warren fastener is rigid in order to withstand repeated pounding so that the fastener can be driven into bone.

Independent claim 29 recites a tissue rivet having a flexible member at the trailing end, the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and being "at least in part curved when said flexible member is in contact with the tissue." Independent claim 60 recites the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and the top of the flexible member being "at least in part concave when said flexible member is in contact with the tissue." Independent claim 100 recites the flexible member being "at least in part curved when said bottom of said flexible member contacts the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claims 29 and 100, or at least in part concave as recited in claim 60.

Independent claim 144 recites at least a portion of the bottom of the flexible member "forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees." Independent claim 211 recites a member having a bottom, "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft." Warren teaches a fastener with a head

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having a bottom that is perpendicular to the mid-longitudinal axis of the shank. (See Warren, Fig. 8). Warren does not teach or suggest a tissue rivet having the angular relationship as recited in independent claims 144 and 211.

Independent claim 176 recites the flexible member having an outer perimeter, "at least a portion of said outer perimeter being flexible relative to said shaft when said rivet is inserted into the tissue." Independent claim 242 recites a member, "at least a portion of said member being moveable relative to said shaft between an undeployed position where said bottom surface is not in contact with the tissue and a deployed position where said bottom surface contacts the tissue, said member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape." The head taught by Warren is not configured for moving or flexing, at least due to the greater thickness of the head relative to the shank, and fillet 161 as discussed above. (See, e.g., Warren, Fig. 1). Warren does not teach or suggest a tissue rivet as recited in independent claims 176 and 242.

Independent claim 273 recites a method for holding pieces of tissue together, including the steps of providing the rivet with a member having a bottom, "at least a portion of the member being moveable relative to the shaft between an undeployed position where the bottom surface is not in contact with the tissue and a deployed position where the bottom surface contacts the tissue, the member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape," and "moving at least a portion of the member relative to the shaft to the deployed position." Independent claim 283 recites a method including the step of inserting a rivet into the tissue "until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet." Independent claim 293 recites a method including the step of inserting a rivet into the tissue "until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft,

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at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft." Warren teaches driving the fastener into the bone and so that the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in any one of claim 273, 283, and 293.

Not only does Warren not teach or suggest a rivet as recited in any one of claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293, Warren teaches away from the subject matter of these claims. Warren teaches away from claim 29, 60, 100, 144, 176, 242, 273, and 283 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Applicant's claimed invention because its head is not flexible as recited in independent claims 29, 60, 100, 144, 176, and 283, or moveable as recited in independent claims 242 and 273.

Warren teaches away from claims 211 and 293 by using a head design that must be perpendicular to the longitudinal axis of the shank to facilitate the insertion of the fastener by repeated pounding. (See Warren, Figs. 6-8). If the head of the Warren fastener were angled as recited in claims 211 and 293, repeatedly striking the head as taught by Warren to insert the fastener would be made more difficult because a portion of the vertical insertion force would be translated laterally and the fastener would be more difficult to insert. Accordingly, Applicant submits that Warren teaches away from Applicant's claimed invention. (See MPEP §2141.02, "Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims," page 2100-103, col. 1 (May 2004)).

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B. The Examiner's rationale for supporting the rejection in view of Warren is inconsistent with the teachings of Warren.

(1) The structure of the head taught by Warren cannot be ignored.

The Examiner states that "[d]ue to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that [the] rivet of Warren would comprehend the claimed resilient characteristic at least to some extent." (Office Action, paragraph bridging pages 4 and 5). By focusing only on the material of the Warren fastener, the Examiner is ignoring the structure of the fastener taught by Warren. Warren teaches that head 110 has a thickness greater than the wall thickness of the shank. (See Warren, col. 3, lines 38-40, 46, and 47; col. 4, lines 66-67). The thickness of the shank wall is obtained by subtracting the rib diameter, 0.157 inches, from the diameter of the internal bore, 0.048 inches, and then dividing the result by two to arrive at 0.0545 inches, which is less than the 0.069 inch thickness of the head. If the head of the Warren fastener were flexible enough to deform to conform to the surface of the tissue as recited, for example, in claims 29 and 60, then shank of the Warren fastener would have insufficient rigidity to withstand repeated blows to be driven into the bone. This result follows because the head has a thickness greater than the wall of the shank. (See, e.g., Warren, Fig. 1). Thus, if the head were modified to be sufficiently flexible as recited in claims 29 and 60, then the shank would be even more flexible because it is thinner than the head. This, of course, is ignoring any effect of fillet 161, which as discussed above would operate to inhibit flexibility. Modifying the head of the Warren fastener as suggested by the Examiner would render the shank of the Warren fastener unsatisfactory for its purpose of being able to be driven into bone or bone-like structures. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)).

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(2) The context in which the Warren fastener is used must be considered.

Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, column 5, lines 8-16; and Figs. 6-8). The Examiner states that "[t]he only difference between the claims and Warren's device is that the claims recite that the flexible head member deforms when it is pounded into place. Inherently any head member made of a polymeric material when pounded into place on a surface that is curved or irregular will deform at least to a certain extent." (Office Action, page 5, paragraph bridging pages 4 and 5). First, Applicant's claims do not recite that the flexible member is "pounded into place." Second, assuming *arguendo* that there were any deformation of the head of Warren during insertion, such deformation would be due to the repeated striking of the head to pound the fastener into the bone, not due to the resilient nature of the flexible member conforming to the surface of tissue.

The Examiner further states that "[b]ecause different portions of the head will come into contact with the bone at different times the head will deform as one portion of the head cannot move and other portions continue to move closer to the bone." (Office Action, page 5, paragraph bridging pages 4 and 5). Applicant respectfully submits that the Examiner is ignoring the context in which Warren teaches using the fastener. Warren teaches driving the fastener through ligament 200 and into bone 300. (Warren, col. 5, lines 13-14; Figs. 7 and 8). As the fastener is pounded into the bone, the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16). The head taught by Warren is not designed to be used against bone, but rather "ligaments or ligament-like objects." (Warren, col. 7, lines 28-29). As the head of the Warren fastener is pounded in, it will contact the softer ligament. Thus, any deformation as between the head and the ligament will be confined to the ligament deforming, not the head. To attempt to use the fastener of Warren to attach only bone segments together would change the principal operation of the Warren fastener. The Examiner's modification of the principal of operation of the Warren fastener is not permissible. (See MPEP §

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2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference," page 2100-132, col. 1 (May 2004)).

(3) The Examiner's redesign of the Warren fastener is without teaching or suggestion.

The Examiner states that "Warren teaches that the fastener can be thinner." (Office Action, page 5, paragraph bridging pages 5 and 6). The Examiner then redesigns the Warren fastener to fit within the scope of Applicant's claimed invention. (See Office Action, paragraph bridging pages 5 and 6). The Examiner states that a thinner fastener "would then result in a head member that would flex as it is forced into contact with the bone," and that finding the right dimensions "would result in a head that flexes during implantation." (Office Action, paragraph bridging pages 5 and 6). Applicant respectfully submits that the Examiner's redesign of the Warren fastener is improper. First, the Examiner has not provided any motivation as to why one would modify the Warren fastener to have "a head that flexes." (Office Action, page 6, paragraph bridging pages 5 and 6) (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Second, modifying the Warren fastener as suggested by the Examiner render it unsuitable for its intended purpose of being able to be pounded into bone as taught by Warren. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For Its Intended Purpose," page 2100-131, col. 2 (May 2004)). Accordingly, the Examiner's proposed redesign of the Warren fastener cannot be applied in the rejection.

(4) The Examiner is using impermissible hindsight.

Applicant also submits that the Examiner is using impermissible hindsight in order to fashion a motivation to support the rejection. The Examiner states that "it would have been obvious to modify the rivet of Warren" to have "a head that flexes."

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(Office Action, page 6, paragraph bridging pages 5 and 6). Such a motivation is not suggested in the art cited by the Examiner. In the specification, Applicant teaches a flexible member that is "sufficiently flexible so as to be able to conform to the angle of the meniscus." (Specification, page 6, lines 31-33). Applicant submits that prior to Applicant's teachings, there was no motivation to have a head that flexes.

It is respectfully submitted that the Examiner is using impermissible hindsight by gleaned the motivation used to reject the present claims over Warren from Applicant's own teachings in the specification. (See MPEP § 2141.01(III), page 2100-98, col. 2 (May 2004) ("[i]t is difficult but necessary that the decision-maker forget what he or she has been taught...about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." (citation omitted)). Applicant respectfully submits that the rejection was not framed with the mind of one skilled in the art presented only with the references and then-commonly accepted wisdom in the art, but with the guidance of Applicant's teachings. It is therefore submitted that a *prima facie* case of obviousness has not been established.

The Examiner rejected 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,976,715 to Bays et al. ("Bays") in view of Warren. Applicant respectfully traverses the rejection and submits that it cannot be maintained for the reasons stated below.

A. The motivation used by the Examiner to support the combination of references is unsupported.

Bays teaches a tack member 10 for repairing damaged tissue, a hollow applicator 20, and a needle 30 slidably receivable in applicator 20 and tack member 10. (See Bays, column 4, line 67 through column 5, line 5). Applicator 20 has a

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J-shaped configuration at its forward end 21 (see Bays, Fig. 1) which serves to restrain a grip portion 15 of the tack member. (Bays, column 5, lines 5-18).

The Examiner contends that "it would have been obvious to modify the rivet of Bays as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough resulting in a head that flexes during implantation." (Office Action, page 7, paragraph 1). Applicant respectfully submits that this motivation is unsupportable because it does not state why one of ordinary skill in the art would want to modify the head of Bays to flex. (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Accordingly, Applicant respectfully submits that the rejection is unsustainable and must be withdrawn.

B. The combination of Bays and Warren teach away from Applicant's claimed invention.

Even assuming *arguendo*, that there was proper motivation to combine the repair tack of Bays with the fastener of Warren, the combination teaches away from Applicant's claimed invention. The J-configuration of the Bays applicator serves to restrain the head portion "against twisting or rotation about any axis extending vertically." (Bays, column 5, lines 16 and 17). In order to serve its intended purpose, the head portion adapted to be used with the applicator of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. Applicant submits that if head 110 of the Warren fastener has the sufficient rigidity for use with the J-configuration of the applicator of Bays, then the proposed combination would not render Applicant's claimed invention obvious since a fastener head that is rigid enough to withstand axial movement and twisting or rotation about any vertical axis cannot be fairly said to be sufficiently flexible within the scope of Applicant's claimed invention.

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C. The proposed combination still does not yield Applicant's claimed invention.

Even if the combination of Bays and Warren could be properly maintained, Applicant submits that the combination does not teach or suggest a tissue rivet as claimed by Applicant. Both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet as recited in any one of independent claims 29, 60, 100, 144, 176, 211, and 242, or a method as recited in any one of claims 273, 283, and 293. (The specific portions of each of these claims recited above in Applicant's rebuttal of Warren are equally applicable to the rejection in view of Bays and Warren).

The Examiner rejected claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan"); U.S. Patent No. 4,728,238 to Chisholm et al. ("Chisholm") or U.S. Patent No. 4,422,276 to Paravano ("Paravano"). Applicant respectfully traverses the rejection.

Applicant submits that Chisholm and Paravano are non-analogous art. The claims of the present invention are directed to a surgical tissue rivet and methods of surgery. Chisholm is directed to a plastic drive fastener for use in the automotive industry. (Chisholm, col. 2, lines 22-26). In particular, Chisholm states that "[t]he importance of the present invention relates to a plastic drive fastener which can be readily installed into an apertured panel or a bore within a thick panel in which the removal force is far in excess of the force of installation." (Chisholm, col. 2, lines 22-31). Paravano relates to "[a] door trim fastener assembly [that] includes a headed fastener overlying the backing layer of a trim panel and having a shank which extends through a slot in the trim panel." (Paravano, Abstract). Applicant states in the background of the specification that rivet-like tabs used in the automotive industry are "relatively large and have no application in a surgical procedure." (Specification, page 3, lines 18-20).

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Applicant submits that the surgical field and the automotive field are non-analogous fields of endeavor and therefore cannot be combined to arrive at Applicant's claimed invention. (See MPEP § 2141.01(a), "Analogy in the mechanical arts," page 2100-100, col. 1 (May 2004), which discusses *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992)("The court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments."). Accordingly, Applicant submits that the rejection is unsustainable and must be withdrawn. Applicant notes that Chisholm was also cited in the Office Action dated July 11, 1994, but was successfully overcome after Applicant's reply dated March 17, 1995 in which Chisholm was asserted as being non-analogous art.

Applicant submits that even if Chisholm and Paravano are not included in the proposed combination of references to reject the claims under 35 U.S.C. 103(a), the rejections over claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 are rendered moot at least because they depend from an allowable independent claim, or claims dependent therefrom.

The Examiner rejected claims 87, 88, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and Duncan, and further in view of U.S. Patent No. 4,338,835 to Simons ("Simmons"). Applicant respectfully traverses the rejection for at least the reasons stated below.

A. The alleged equivalent must be an art recognized equivalent.

Bays teaches a hollow applicator 20, a needle 30 slidably receivable in applicator 20, and tack member 10. (Bays, column 4, line 67 through column 5, line 5). Applicator 20 has a J-shaped configuration at its forward end 21 (Bays, Fig. 1) which serves to restrain a grip portion 15 of the tack member. (Bays, column 5, lines 5-18).

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Simmons teaches a driver 10 having a driver head 16 with four curved convex surfaces 22. (Simmons, col. 2, lines 49-57; Figs. 1 and 4). Simmons does not teach or suggest that driver head 16 is equivalent to the needle and J-shaped applicator combination of Bays. The Examiner states that "it would have been obvious to one of ordinary skill in the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simmons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place." (Office Action, page 8, paragraph 2). According to the MPEP, "[i]n order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." (MPEP § 2144.06, page 2100-117, col. 2 (May 2004), citing *In re Ruff*, 256 F.2d 590 (CCPA 1958)). Since Simmons fails to teach that his driver head is equivalent to the applicator configuration taught by Bays, the driver taught by Simmons cannot be cited as an obvious equivalent.

B. The proposed combination still fails to yield Applicant's claimed invention.

Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is configured to cooperatively engage a driver instrument, as recited in claims 87 and 131, or where the depression is at least in part spherical as recited in claims 88 and 132. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Applicant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

Applicant further submits that the cited art, whether alone or in proper combination, fails to teach or suggest the subject matter of Applicant's dependent

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claims. For example, dependent claims 32, 64, and 104 recite the flexible member having an outer edge that is beveled. In the Office Action, the Examiner contends that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (Office Action, page 6, paragraph 1).

Pursuant to MPEP 2144.03(c), Applicant traverses the Examiner's assertion that the skin rubbing over the head of a tissue fastener is a well-recognized problem in the art that is solved by making the heads flush. (See MPEP 2144.03(c), "[i]f Applicant challenges a factual assertion as not properly Officially Noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence," page 2100-112, col. 1 (May 2004)). First, the skin of a patient makes no contact with a trailing end of a rivet that is inserted into the meniscus of the knee. The flexible member of the rivet taught by Applicant is configured to minimize interference with normal knee-joint motion, not skin abrasion. Second, none of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, a flexible member having a beveled outer edge. (See, e.g., Bays, Fig. 3; Warren, Fig. 8; and Duncan, Fig. 9). Also, according to the MPEP, "[i]f the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2)." (MPEP 2144.03(c), page 2100-112, cols. 1 and 2 (May 2004)). Accordingly, Applicant respectfully requests that the rejection be withdrawn, or if the Examiner maintains the rejection, that the required evidence be provided in accordance with MPEP 2144.03(c).

Dependent claims 42, 74, 116, 157, 192, 223, and 254 recite a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

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Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Applicant submits that claims 42, 74, 116, 157, 192, 223, and 254 are allowable over the analogous cited art.

Dependent claims 277, 286, and 295 recite the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Applicant submits that claims 277, 286, and 295 are allowable over the cited art.

Dependent claims 281, 291, and 299 recite the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Applicant submits that claims 281, 291, and 299 are allowable over the cited art.

Dependent claim 288 recites the step of "snap-fitting the rivet onto a portion of the driving instrument." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Applicant submits that claim 288 is allowable over the cited art.

Applicant submits that independent claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293 are patentable over the art of record and that dependent claims 30-59,

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61-99, 101-143, 145-175, 177-210, 212-241, 243-272, 274-282, 284-292, and 294-300 dependent from one of independent claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: September 20, 2004

By: 

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